REMARKS

The Office Action dated September 23, 2008 presents examination of claims 89-120.

Amendments to the Claims

Applicants have amended claim 104 to be independent. Applicants note that no rejection was applied to claim 104, therefore, Applicants request that the Examiner allow claim 104.

Claims 89 and 90 have been amended to recite that the compound shows "an effect only at the applied location." Support for this amendment is found in the Specification at page 39, lines 9-14. Claims 89 and 90 have also been amended to recite an allergic disease. Support is found in the Specification at page 2, line 25.

Claims 91 and 96 have been amended to agree with the scope of claim 90.

Claims 106 and 108 have been amended to agree with the scope of claim 100.

Claim 109 has been cancelled as it was incorporated into claim 89. Claim 110 has been amended to depend from claim 89 or 90.

Claim 115 has been amended for wording.

Claim 117 has been amended to clarify serum. Support for this amendment is found in the Specification at page 41, lines 26-28 to page 42, line 1.

Claim 120 has been amended to clarify the compound. Support for this amendment is found in the Specification at page 84, line 14, Example 76.

New claims 121-131 have been added. Support for these claims is found in the originally filed claims.

No new matter has been added.

Rejections under 35 U.S.C. §§ 102/103

The Examiner rejects claims 89-99, and 109-113 under 35 U.S.C. §§ 102(b)/103 as anticipated and/or obvious by U.S. Patent 6,329,381 (hereinafter '381). Applicants submit that this rejection should not be applied to the present claims.

Applicants first point out that claims 89 and 90 have been amended. Applicants submit that those amendments remove the present claims from the scope of the prior art. For this reason alone, Applicants request that the Examiner withdraw the rejection.

Second, Applicants point out that '381 explicitly discloses over 125 compounds and implicitly discloses any number of compounds, but does not disclose their half-lives. Third, '381 discloses *transdermal systematic* delivery rather than *local topical* delivery. Asthma is not taught by '381, as conceded by the Examiner. Applicants note that the only compounds of the present invention which could possibly overlap those of '381 are when A is an aromatic ring, m=0, and n= 0 or 1.[1]

Systemic v. Local Administration

The Examiner states that it is "simply untrue" that transdermal administration is not equivalent to topical administration. The Examiner concludes that "[a] transdermal medicine is by its very nature topically applied. Dermis means skin. Transdermal formulations . . . are applied to the skin." (Office Action, page 4). Applicants submit that a topical administration is NOT a systemic administration. Moreover, the Examiner should only take official notice of a fact, unsupported by documentary evidence only when it is "common knowledge in the art" which is "capable of instant and unquestionable demonstration as being well known." (MPEP 2144.03(A)). In the present instance, both transdermal and topical are terms of art.

[1] The only group shown to attach to the benzene ring of '381 is F, though the claims state that that group can be any of a variety of alkyls groups etc..

Thus, Applicants submit that this amendment to claim 89 overcomes the Examiner's rejection with regard to claim 89.

Sprays

The Examiner states that '381 mentions "propellants which are used only in sprays. . . [which] have two uses, into the lungs, and again, onto the skin." However, in the claim directed to "inhalation" the ring A is recited as being a heteroaromatic ring (claims 100-106), or in instances where ring A is benzene, the ring A is substituted by an alkyl amino substituted ester group (claims 107-114). The particular compounds of claim 120 are not mentioned in the '381 patent either. Thus, Applicants request that the Examiner withdraw the rejection regarding claims 113 and 120.

With regard to spraying the compound "onto the skin," which the Examiner suggests is a "topical" administration. Applicants point to the fact that the method claims 89-99 and 115-119 are intended for a "topical" administration "wherein said medicament shows an effect only at the applied location." (Claims 89 and 90). It is not disclosed or suggested by '381 that a "propellant" would have only a local effect.

Inherency

The Examiner rejects the claims based on inherency. Applicants submit that the Examiner has failed to establish a *prima facie* case of anticipation.

For anticipation under 35 U.S.C. §102, the reference must teach each and every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present". *In re Robertson*,

169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Id.*

The Examiner uses the doctrine of inherency to reject the claims, stating that "the unknown property is the [] half-life." (Office Action, page 6). Therefore, Applicants point out that the "half-life" would only apply to claims 111 and 112, if at all.

Applicants submit that the Examiner's interpretation of inherency with regard to the "half life" of the claimed compounds is inappropriate and amounts to legal error. Applicants submit that half life is condition dependent. Thus, even if the prior art disclosed one of the claimed compounds, then it does not necessarily follow that the compound would be administered topically, and that the half life of that compound would be identical to the administration disclosed in the present application. Thus, Applicants submit that the Examiner's reliance on inherency fails as a matter of law.

Moreover, the Examiner himself suggests that "the legal circumstances of inherency-in-the-prior-art do not apply." (Office Action, page 6, line 20). Applicants heartily agree, so much so that the doctrine of inherency should not be applied at all. Therefore, Applicants request that the Examiner withdraw the § 102 rejection of claims 111 and 112.

The Examiner states that he does not make the argument that a "similar compound will have identical properties." However, that is exactly the argument the Examiner has made. The Examiner states that "[r]ecitation of a property, inherently possessed by the prior art thing, does not distinguish a claim drawn to those things from the prior art."

However, the Examiner cannot suggest that a "similar" compound is anticipated by a different compound. Anticipation requires that each and every element be explicitly or implicitly disclosed in the prior art. Thus, a "similar" compound is not sufficient.

In addition, if the Examiner intends to apply the "inherency" doctrine to an obviousness rejection, that application is improper. "That which may be inherent is not necessarily known. *Obviousness cannot be predicated on what is unknown.*" *In re Rijckaert,* 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). Thus, the Examiner's obviousness rejection of claims 111 and 112 is improper as a matter of law. Applicants request that it be withdrawn.

For any and all of the above reasons, the instant rejection should not be applied to the present claims.

Rejections for indefiniteness

Claims 89, 111, 117, 120, and 115 are rejected under 35 USC § 112, second paragraph as being indefinite. Applicants submit that the present claim language is not indefinite and is readily susceptible to interpretation.

Claims 89 and 115

The Examiner rejects claims 89 and 115 for the recitation of "regulating immune response without systemic pharmacological activity." Applicants have amended claims 89, 90 and 115 to recite "and wherein said medicament shows an effect only at the applied location." Applicants submit that there can be a localized immune response. Accordingly, Applicants submit that the claims are clear. Applicants submit that this amendment and these remarks overcome the Examiner's rejection. Applicants request that it be withdrawn.

Claim 120

The Examiner rejects claim 120 because "the 13th from last compound on page 114 is unclear." Claims 120 has been amended. Applicants request that the rejection be withdrawn, and since claim 120 has only been rejected under non-statutory obviousness type double patenting, request that the Examiner allow claim 120.

Claims 111 and 117

The Examiner rejects claims 111 and 117 stating that "there is no way of telling how this measurement must be done, as it is not clear even what type of serum is intended. The word can refer to any kind of clear bodily fluid." Applicants submit that the term "serum" is expressly defined in the Specification on page 41, lines 27 to page 42, line 2. Applicants submit that in light of the teachings in the Specification one of skill in the art would understand what is meant by the term "serum." Applicants request that the rejection be withdrawn.

Rejection for lack of enablement

Claims 89-99, 109, 111-115, and 117-119 are rejected under 35 USC § 112, first paragraph, for lack of enablement of the claimed subject matter, with respect to demonstration of therapeutic utility.

Applicants first note that claims 89 and 90 have been amended. A significant number of the compounds claimed in claims 89 and 90 are shown to be effective in the working examples, specifically, in Tables 1, 2, 5, and 6 of the present Specification. These tables reflect the data from the in vitro mouse spleen cell model and the in vivo asthma model. Accordingly, Applicants suggest that the claims are enabled.

Applicants also wish to point out that the Examiner's assessment of the predictability of the art is relevant to the claimed invention. The Examiner states that "physiology is generally considered to be an unpredictable factor." (Office Action, page 14). Applicants disagree. The Examiner does not support this statement with any documentary evidence, and the statement is so broad as to be meaningless to the present application. For instance, physiology could be anything from aging to cancer. Aging is predictable. Some cancers may not be. Applicants request that the Examiner apply a meaningful paradigm to demonstrate the art and to support any conclusions based thereon with documentary evidence or a rationale that is capable of instant and unquestionable demonstration.

Applicants also note that the standard for patentability is a preponderance of the evidence, as shown in the MPEP page 700-20. "The standard to be applied in all cases is the preponderance of the evidence test. . . . [A]n Examiner should reject a claim if, in view of the prior art and evidence of record, it is more likely than not that the claim is unpatentable." *Id.*

Accordingly, the full scope of the present claims must be taken to be enabled, and the instant rejection should not be applied to the present claims.

Obviousness-type double patenting

Claims 89-95, 97-103, 105-120 are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-19 and 21 of co-pending application 10/594,074.

Applicants note that co-pending application 10/594,074 has not yet issued. As claims 100-103, 105-108, 116 and 120 are only rejected for obviousness-type double patenting, Applicants request that these claims be allowed. The claims of 10/594,074 may be subject to an obviousness type double-patenting rejection in the future, however, because those claims have not yet issued it is improper to impose such a rejection in the present file.

Conclusion

If the Examiner has any questions concerning this application, the Examiner is requested to contact Mark J. Nuell, Reg. No. 36,623 at the telephone number of (858) 792-8855. Facsimile communications may be sent to the undersigned at the facsimile number of (858) 792-3785.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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